IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI

JOHN RAPA,	)	
	)	
Plaintiff	)	
	)	
vs.	)	**CASE No.**
	)	
NOVARTIS PHARMACEUTICAL CORPORATION,	)	
	)	
Defendant.	)	
	)	
	)	
	)	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff John H. Rapa ("Plaintiff"), by his attorneys, for his Complaint against Defendant Novartis Pharmaceuticals Corporation ("Defendant"), alleges:

1. This is a civil action for damages suffered by Plaintiff as a result of his being prescribed and injected with Defendant's drug Aredia.

PARTIES

2. Plaintiff is a citizen and resident of the State of Missouri, residing in Hazelwood, Missouri.

3. At all times herein mentioned, Defendant was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

4. During all times relative hereto, Defendant was in the business of manufacturing, marketing, distributing, promoting, testing, labeling and selling Aredia.

JURISDICTION

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars ($75,000.00) and

Plaintiff is a citizen of a State which is different from the State where defendant is incorporated and has its principal place of business.

FACTUAL BACKGROUND

6. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

7. Aredia ("pamidronate disodium") is a bisphosphonate. The principal action of Aredia is inhibition of bone resorption. Bisphosphonates prevent and treat osteoporosis in post-menopausal women. Stronger forms of bisphosphonates are used in the management of advanced cancers that have metastasized to the bone. When bisphosphonates are given in cancer chemotherapy, drugs like Aredia are administered intravenously and/or by injection and usually for longer periods.

8. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drugs contained no warning about osteonecrosis of the jaw or other bone structure.

9. In 2002 or before, Defendant received information from a physician that several of the physician's patients who were given Aredia were diagnosed with osteonecrosis of the jaw and that he believed a causal relationship existed between the use of Aredia and osteonecrosis of the jaw.

10. Aredia increases the risk of osteonecrosis of the jaw. Aredia causes osteonecrosis of the bone. Nevertheless, Defendant failed to warn consumers adequately of this risk.

11. Defendant made a labeling change in October 2003, but this change was also inadequate to warn consumers, and remains so to this date.

12. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

13. Defendant sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of Aredia in September 2004 and May 2005.

14. Plaintiff was prescribed and given Aredia.

15. As a result of being given and/or injected with Aredia, Plaintiff developed osteonecrosis of the jaw.

16. As a result of being given and/or injected with Aredia, Plaintiff suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe past and future pain and suffering;

c. severe past and future mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. past and future medical care and monitoring; and

g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability]

17. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 16 of the Complaint as if they were set forth here in full.

18. Defendant was engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing Aredia in interstate commerce, and which it then sold and distributed throughout the world.

19. Plaintiff took Aredia in a reasonably foreseeable manner.

20. Aredia reached Plaintiff without a substantial change in condition

21. Aredia increased the risk of osteonecrosis of the jaw. Aredia caused osteonecrosis of the jaw. Therefore, Aredia is an "unreasonably dangerous/defective product" due to Defendant's failure to warn Plaintiff.

22. This unreasonably dangerous/defective product increased the risk of osteonecrosis of the jaw. It caused Aredia-induced osteonecrosis. Plaintiff suffered osteonecrosis of the jaw. Plaintiff sustained compensatory damages in an amount to be proven at trial.

23. Defendant is strictly liable to Plaintiff. Additionally, Defendant's conduct was "reckless" as defined by *Hodges v. S.C. Toof & Co.*, 833 S.W. 2d 896, 901 (Tenn. 1992). To this day, Defendant has not warned dentists across the nation of this danger or how to monitor and treat patients who took Aredia as prescribed. Therefore, Plaintiff seeks imposition of punitive damages in order to punish Defendant and deter other drug companies form the same wrongdoing.

SECOND CLAIM FOR RELIEF

[Negligence]

24. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 16 of the Complaint as if they were set forth here in full.

25. Defendant owes Plaintiff a common law duty to use reasonable care in manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, and advertising Aredia. This duty included a warning about the danger of Aredia-induced osteonecrosis.

26. Defendant breaded the duty of care in one or more of the following respects:

a. Failing to test and inspect Aredia in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose of which it was designed, manufactured, and sold;

b. Failing to utilize and implement a reasonably safe design in the manufacture of Aredia;

c. Failing to manufacture Aredia in a reasonably safe condition;

d. Failing to warn Plaintiff of the danger of Aredia-induced osteonecrosis.

e. Failing to label Aredia reasonably as to warn the Plaintiff of the danger of Aredia-induced osteonecrosis; and

f. Manufacturing Aredia which is an unreasonably dangerous/defective drug.

27. Furthermore, Defendant is guilty of negligence *per se*. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et.seq,* and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes and regulations. Defendant's acts and

omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se.*

28. Defendant failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. Plaintiff is part of this class. Therefore, Defendant is negligent *per se* in the following respects:

(a) The labeling lacked adequate information for the use of the drug Aredia (21 C.F.R. Section 201.56[a] and [d]);

(b) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drug (21 C.F.R. 201.57 [e]);

(c) There was inadequate information for patients for the safe and effective use of Defendant's drug (21 C.F.R. 201.57[f][2]);

(d) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendant's drug (21 C.F.R. 201.57[f][2]); and

(e) The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

29. Defendant's negligence is a legal cause of all damages. Plaintiff suffered osteonecrosis of the jaw. Plaintiff has sustained compensatory damages in an amount to be proven at trial.

THIRD CLAIM FOR RELIEF

[Medical Monitoring]

30. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 16 of the Complaint as if they were set forth here in full.

31. Plaintiff was significantly exposed to a hazardous substance ("Aredia") throughout the intentional, negligent, or wrongful actions of Defendant.

32. As a result of this exposure, Plaintiff suffered a significantly increased risk of developing Aredia-induced osteonecrosis of the jaw, which is latent and serious.

33. The increased risk of Aredia-induced osteonecrosis makes periodic, diagnostic medical examinations reasonably necessary. Monitoring and testing procedures already exist to make an early detection, diagnosis and treatment of Aredia-induced osteonecrosis possible and beneficial.

34. Defendant is liable for all costs associated with a comprehensive, court-supervised medical monitoring program for the Plaintiff. This medical monitoring program, funding by Defendant, will assist the Plaintiff and future Plaintiffs in the early detections and treatment of Aredia-induced osteonecrosis. Such program should include the following:

a. A method to notify individuals who took Aredia of the risk of Aredia-induced osteonecrosis;

b. Provision for the accumulation and analysis of relevant medical and demographic information including, but not limited to, the results of all appropriate diagnostic tests performed as part of a medical research and education fund;

c. Provision for the creation, maintenance, and operation of a medical registry in which relevant demographic and medical information is gathered, maintained, and analyzed;

d. Provision for medical research concerning the incidence, prevalence, natural course and history, diagnosis, and treatment of Aredia-induced osteonecrosis; and

e. Publication and other dissemination of all information to relevant health care providers, including physicians, oral surgeons, and dentists.

35. Because timing and technique are important elements in the prevention or treatment of Aredia-induced osteonecrosis, this proposed Medical Monitoring Program will help health care providers advise their patients and take steps that substantially reduce the risk of Aredia-induced osteonecrosis.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

36. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 16 of the Complaint as if they were set forth here in full.

37. Defendant expressly warranted, by and through statements made by Defendant or its authorized agents, that Aredia was safe, effective, and fit for the intended use.

38. Plaintiff, and his agents, relied on the skill, judgment and representations of Defendant.

39. Aredia did not conform to Defendant's express warranties in that Aredia was not safe and fit for the intended use because Aredia caused serious adverse side effects, including osteonecrosis of the jaw.

40. As the proximate cause and result of Defendant's breach of its express warranties, Plaintiff was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

41. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 16 of the Complaint as if they were set forth here in full.

42. Defendant impliedly warranted to Plaintiff, and his agents, that Aredia was of merchantable quality and was safe and fit for the intended use.

43. Plaintiff, and his agents, relied on Defendant's skill and judgment.

44. Aredia was not of merchantable quality or safe and fit for the intended use in that Aredia caused serious adverse side effects, including osteonecrosis of the jaw.

45. As the proximate cause and result of Defendant's breach of its implied warranties, Plaintiff was injured.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff John H. Rapa respectfully prays for relief and judgment against the Defendant as follows:

a. Declare that Aredia is "unreasonably dangerous or defective."

b. Award compensatory and punitive damages in an amount to be proven at trial;

c. Award attorney's fees and costs, plus interest, as allowed by law;

d. Hold Defendant financially responsible for notifying the Plaintiff of Aredia-induced osteonecrosis and the need for medical monitoring;

e. Order Defendant to fund a Court-approved medical monitoring program for Plaintiff and future Plaintiffs, which includes payment or reimbursement of medical screening and treatment related to Aredia-induced osteonecrosis; and

f. Order such other and further judicial determinations, and relief, as may be appropriate under the circumstances.

JURY TRIAL DEMAND

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

SIMON PASSANANTE, PC

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